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10/809,236	03/25/2004	Mehran Bashiri	S63.2P-11058-US02	9063

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EXAMINER	
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ART UNIT	PAPER NUMBER
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/809,236	BASHIRI ET AL.	
	Examiner	Art Unit	
	KATHLEEN SONNETT	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24 and 26-45* is/are pending in the application.

4a) Of the above claim(s) *41-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-24, 26-40,44 and 45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-45 are pending. Claims 41-43 are withdrawn.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 1-7, 26-32, and 40** are rejected under 35 U.S.C. 102(b) as being anticipated by Sgro (US 5,735,871). Sgro discloses a stent assembly comprising a stent, the stent having a proximal and distal end and being configurable between an unexpanded and expanded state, the stent comprising a first stent backbone (an element 21 and 22 which are adjacent) which extends from proximal to distal end of stent and being oriented substantially parallel to the longitudinal axis of the stent, and a plurality of interconnected first and second stent members, the first stent members (remaining elements 21 and 22) being oriented substantially longitudinally in the unexpanded and expanded state, and each of the second stent members (7) being oriented in a substantially longitudinal direction in the unexpanded state and in a substantially circumferential direction in the expanded state. Sgro discloses that relative movement of 21 with respect to 22 results in expansion and collapsing of the stent, which will cause members 7 to change from substantially longitudinal to substantially circumferential. The first stent backbone has greater column strength than the plurality of interconnected stent members since it comprises two adjacent longitudinal members and connecting members 7 between them as compared to a single element 21, 22, or 7.

4. Regarding claim 2, the backbone comprises a plurality of first stent members (adjacent 21 and 22 and members 7 between them).

5. Regarding claim 3, the first backbone has a greater thickness than each of the plurality of interconnected first and second stent members. The first backbone thickness can be considered the thickness of an adjacent 21 and 22 plus the thickness of second stent member 7 between them.

6. Regarding claims 4-7, the second backbone may be any other longitudinal member other than the longitudinal member that has been designated the first backbone. The second backbone may comprise two adjacent first stent members. The two adjacent first stent members that make up the second backbone are spaced apart from one another.

7. Regarding claim 26, adjacent interconnected first and second stent members form closed loops (see fig. 1, 2).

8. Regarding claims 27-32, as seen in fig. 2, the cross section of elements 21 and 22 are circular and therefore at least one of the first stent members (one of elements 21 that does not form backbone) comprises a substantially curved portion. The second stent members are straight. Regarding claims 29-32, the first and second backbones (adjacent 21 and 22 and another element 21, respectively) comprise at least one substantially curved portion since they are formed of cylindrical members. They also can be considered to comprise a substantially straight portion since they are straight in the longitudinal direction.

9. Regarding claim 40, elements 21 and 22 are tubes since they are cylindrical.

10. **Claims 1-7, 26, 28, 30, 32, and 38-39** are rejected under 35 U.S.C. 102(b) as being anticipated by Sgro (US 5,496,365). Sgro discloses a stent assembly comprising a stent, the stent having a proximal and distal end and being configurable between an unexpanded and expanded state, the stent comprising a first stent backbone (adjacent 3 and 4) which extends

from proximal to distal end of stent and being oriented substantially parallel to the longitudinal axis of the stent, and a plurality of interconnected first and second stent members, the first stent members (members parallel to 3, 4) being oriented substantially longitudinally in the unexpanded and expanded state, and each of the second stent members (2) being oriented in a substantially longitudinal direction in the unexpanded state and in a substantially circumferential direction in the expanded state (see fig. 7, 8). Sgro discloses that relative movement of 8 with respect to 9 results in expansion and collapsing of the stent, which will cause members 2 to change from substantially longitudinal to substantially circumferential. The first stent backbone has greater column strength than the plurality of interconnected stent members since it comprises two adjacent longitudinal members and connecting members 2 between them as compared to a single element 5 or 2.

11. Regarding claim 2, the backbone comprises a plurality of first stent members (adjacent 3, 4).

12. Regarding claim 3, the first backbone has a greater thickness than each of the plurality of interconnected first and second stent members. The first backbone thickness can be considered the thickness of an adjacent 3 and 4 plus the thickness of second stent member 2 between them.

13. Regarding claims 4-7, the second backbone may be any other longitudinal member other than the longitudinal member that has been designated the first backbone. The second backbone may comprise two adjacent first stent members. The two adjacent first stent members that make up the second backbone are spaced apart from one another.

14. Regarding claim 26, adjacent interconnected first and second stent members form closed loops (see fig. 5).

15. Regarding claims 28, 30, and 32, the first stent members and second stent members are straight. The first and second backbones can be considered to comprise a substantially straight portion since they are straight in the longitudinal direction.

16. Regarding claims 38 and 39, the first backbone and second back bone have proximal ends and distal ends that are longitudinally and circumferentially offset in both the unexpanded and expanded configuration. That is, the second backbone comprises just one longitudinal member and can be chosen so that it is not aligned with the proximal-most end of the first backbone, which comprises two longitudinal members. It is also noted that the expanded configuration does not necessitate that the device is fully expanded and therefore the proximal ends can be offset in a partially expanded configuration.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. **Claims 8-11, 13-15, and 34-37** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sgro (US 5,496,365) in view of Bashiri et al. (US 6,165,178). Sgro discloses the invention substantially as stated above but fails to disclose a push wire having a distal end that is removably engaged to a proximal end of the stent, the first backbone extending from the distal end of the push wire. Sgro instead discloses a stent that is connected to two cylinders whose relative movement causes expansion and contraction of the stent.

19. However, as is well known in the art, stents are sometimes made of nitinol in order to be self-expanding. This reduces the number of mechanical actions that are needed to deploy the stent. When the stent is self-expandable, it can be used with the wire taught by Bashiri et al. (see fig. 15; col. 9 ll. 25-40). The push wire (194) is used to position the stent within the desired surgical site. After proper positioning, the stent is released from the push wire when the severable junction (196) is electrolytically detached. This is advantageous when the stent is going to be implanted for an extended period of time. It would have been obvious to one skilled in the art to modify Sgro to make the stent self-expandable so that it can be connected to a single push wire from which it is easily released as taught by Bashiri et al. in order to minimize mechanical actions needed to deploy the stent as well as being able to temporarily implant the stent for an extended period of time. The wire is thermally and electrically conductive.

20. Regarding claims 14 and 15, it would have been obvious to one skilled in the art to construct the electrolytic detachment site to remain attached until the stent is fully deployed. Since the push wire is used to properly position the stent, it would have been obvious to keep this connection present until the stent has reached its fully deployed position. An earlier detachment might result in displacement of the stent since its configuration continues to change slightly until it is fully deployed.

21. Regarding claims 34-36, Bashiri et al. teaches forming part of the severable junctions out of radiopaque material since it is desirable to be able to visualize where the end of the implantable device is located (col. 6, ll. 44-50). Regarding claim 37, Bashiri et al. does not expressly teach a plurality of radiopaque markers but it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art (*St. Regis Paper Co. v. Bemis Co.,* 193 USPQ 8).

22. **Claim 12** is rejected under 35 U.S.C. 103(a) as being unpatentable over Sgro (US 5,496,365) in view of Bashiri et al. as applied to claim 8 and 11 above, and further in view of Camrud et al. (US 6,699,280). Sgro in view of Bashiri et al. discloses the invention substantially including a severable junction between the push wire and the stent but fails to disclose that the severable joint is bioabsorbable.

23. However, Camrud et al. teaches that a severable junction between two portions of an implantable medical device can be formed by a bioabsorbable connection. The bioabsorbable connection degrades upon interaction with fluids within the body lumen to a point at which the two portions break apart (col. 10, ll. 13-20). It would have been obvious to one skilled in the art to further modify Sgro to substitute a bioabsorbable connection as taught by Camrud et al. with the electrolytic detachment site taught by Bashiri et al. since such a modification would have been a simple substitution of known methods of forming a severable junction between two portions of a medical device.

24. **Claims 16-19, 44, and 45** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sgro (US 5,496,365) in view of Bashiri et al. as applied to claim 15 above, and further in view of Ravenscroft (US 5,702,418). Sgro in view of Bashiri et al. discloses the invention substantially but fails to disclose that the device is configurable from the initially deployed configuration to the predeployed configuration.

25. However, Ravencroft teaches using a catheter to keep a self-expanding stent in a collapsed configuration until deployment. Ravencroft further teaches that it is advantageous to have a delivery device that allows partial deployment and retraction of the stent through an attachment at the proximal end of the stent so that the surgeon can recover a stent that is not properly positioned during deployment. It would have been obvious to one skilled in the art to house the stent with a pull wire connected to its proximal end as taught by Bashiri et al. in a

catheter as taught by Ravencroft so that the stent may be partially deployed and then returned back to the predeployed position in order to gain the advantage of being able to recover an incorrectly positioned stent.

26. Regarding claims 18 and 19, the stent cannot be fully deployed at least until the entire stent is free from the catheter. As seen in fig. 15 of Bashiri et al., the very distal end of the push wire is distal of the proximal-most portion of the stent and therefore a portion of the push wire and the stent are free of the lumen before the stent reaches its fully deployed position.

27. Regarding claims 44 and 45, it is old and well known to include radiopaque markers on catheters particularly at their distal ends and is further taught by Bashiri et al. (catheter 102; markers 106). Such a modification would have been obvious to one skilled in the art in order to monitor the position of the catheter within a patient's vasculature.

28. **Claims 20-24 and 33** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sgro (US 5,496,365) in view of Pacetti et al. (US 6,355,058). Sgro discloses the invention substantially as stated above but fails to disclose the particulars of the stent material.

29. Pacetti et al. teaches constructing a stent from a shape memory material such as nitinol and stent can be made from wire (col. 5, ll. 27; col. 7, ll. 43). As is well known in the art, nitinol allows a stent to self-expand reducing any mechanical action needed to change configurations of the stent. Pacetti et al. also teaches including a radiopaque coating with therapeutic agents incorporated therein (abstract; col. 4 ll. 5-8), which allows the stent to be visualized and the surrounding vessel to be treated. It would have been obvious to one skilled in the art to modify Sgro to construct the stent out of nitinol wire with a radiopaque coating that includes therapeutic agents as taught by Pacetti et al. in order to obtain a self-expanding stent that can be viewed as well as a stent that can treat surrounding tissue.

Response to Arguments

30. Applicant's arguments filed 2/14/2008 have been fully considered but they are not persuasive.

31. Applicant argues that the Sgro '871 and Sgro '365 do not disclose second stent members that are oriented in a substantially longitudinal direction in the unexpanded state and being oriented in a substantially circumferential direction in the expanded state. Regarding Sgro '365, when the second stent members (2) are in the orientations shown in figs. 1 and 2, they are considered *substantially* circumferential and *substantially* longitudinal, respectively. This is also shown in figs. 7 and 8. For example, looking at the second stent members (2) in fig. 1, the second stent member has a greater circumferential change than longitudinal change from one end to the other and is considered substantially circumferential. Likewise, the second stent member (2) in fig. 2 has a greater longitudinal change than circumferential change from one end to the other and is considered substantially longitudinal. In the case of Sgro '871, although not illustrated as well in the figures, the disclosure indicates that the longitudinal traction exerted on the stent members (21) with respect to stent members (22) collapses and expands the stent. When stent members (21) are moved away from stent members (22), the second stent members (7) become substantially longitudinal. When the ends of stent members (21) and stent members (22) are moved toward one another such that they substantially line up, the second stent members (7) become substantially circumferential.

32. Regarding applicant's argument that the backbones of Sgro '365 and Sgro '871 as defined by the examiner do not read on the claimed backbone, it is noted that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant argues that the instant claims and supporting disclosure provided by the application

as filed provide clear meaning and understanding of the claimed phrase "first stent backbone" that one of ordinary skill in the art would recognize. Applicant also points out that an inventor can be his/her own lexicographer. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term (*Process Control Corp. v. HydReclaim Corp*., 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999)). The application does not, however, explicitly define that the term backbone can only refer to a single longitudinal member. The embodiments shown and disclosed in the specification and figures are considered preferred embodiments of a backbone. In fact, applicant discloses an embodiment shown in fig. 12 wherein the backbone 45 can comprise one **or more** stent members 46. Looking at Sgro '365, two adjacent longitudinal members (3,4) and their interconnecting pieces (2) can be considered a backbone of the stent. This backbone has greater column strength than the remainder of the stent members since it has at least twice as much material as each of the other stent members.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 4/16/2008

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731